

583-252-0 FWC DIV



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

36

MANFRED ASSMUS ET AL. : EXAMINER: SELLERS

SERIAL NO. 08/813,950

FILED: MARCH 3, 1997 : GROUP ART UNIT: 1712

**FOR: THERMOPLASTIC COATING AND
BINDING AGENT FOR MEDICINAL
FORMS**

SUPPLEMENTAL DECLARATION UNDER 37 C.F.R. §1.132

**ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231**

SIR

I, Manfred Assmus, declare and state as follows:

- 1. I am a coinventor of the above-identified application.**

 - 2. The following additional experiments were carried out by me and/or under my direction and control.**

EXPERIMENTS

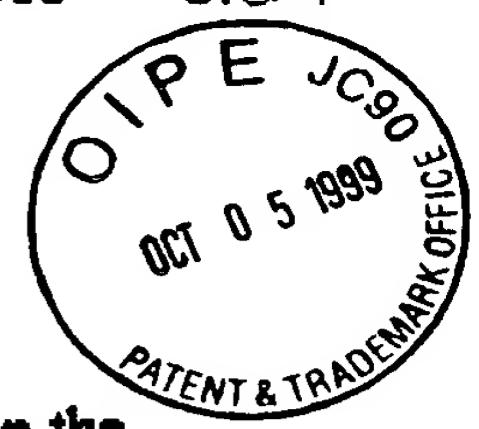
EUDRAGIT RS PO polymer was mixed with 50 wt.% stearyl alcohol, stearic acid, PEG 6000 or with 50 or 80 wt.% glycerol monostearate (GMS).

The mixtures were heated to 65, 100 and 150°C. Samples of the mixtures were watched and photographed under a special melt-microscope (Schmelzmikroskop) in order to show the interaction of the flow improver and the polymer.

No. 1414 P. 7

OBLOUN, SPIVAK

sep. 29, 1999 4:14pm



RESULTS

The results can be seen on the attached photographs and are summarized in the Table below.

TABLE

	65°C	100°C	150°C
Steryl alcohol (50%)	-	+	++
Stearic acid (50%)	-	+	++
PEG 6000 (50%)	-	+	++
GMS (50%)	-	+	++
GMS (80%)	-	+	++

- The polymer particles shown are irregularly shaped with sharp, rough surface. No interaction between the flow improver and the polymer.

+ = The polymer shape/surface is changing from rough to smooth. The interaction is beginning.

++ = The polymer shape/surface is very smooth. Strong interaction between flow improver and polymer.

Conclusion:

None of the melts representative of the prior art mixed at 65 °C were homogeneous. Temperatures under 100 °C thus are not suitable for the purpose of the invention requiring claimed components A) and B) to be miscible in the melt so as to obtain a product as claimed.

As one skilled in this art, I consider the results obtained by the practice of the claimed invention to be unobvious and unexpected and of significant and material import.

-2-

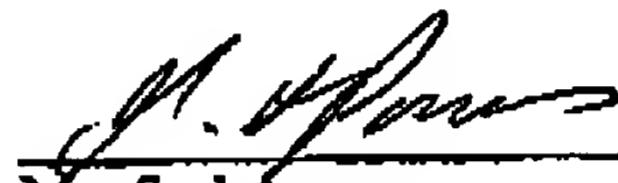
No. 7474 p. 8

OBLOJN, SPIVAK

Sep. 29, 1999 4:14PM

3. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

4. Further, declarant saith not.



Manfred Assmus

30. 9. 99

Date

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

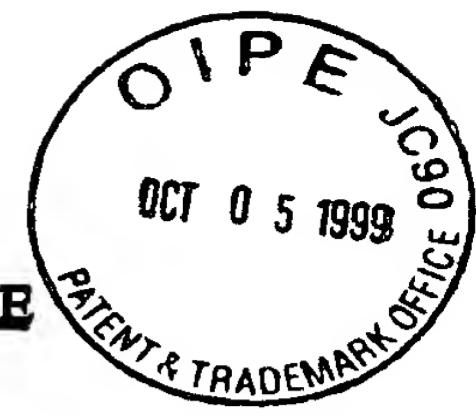
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FORMSDECLARATION UNDER 37 C.F.R. 61.132ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

COPY

SIR:

I, Manfred Assmus, declare and state as follows:

1. I am a coinventor of the above-identified application.
2. The following experiments were carried out by me and/or my supervision and control.

EXPERIMENTS

Examples (under 100°C)

Procedure:

Eudragit® RS PO, a copolymer from 65 wt.% methyl methacrylate, 30 wt.% ethyl acrylate and 5 wt.% 2-tri-methyl-ammoniumethylmethacrylate chloride, was mixed with 20, 30, 40, 50, 60, 70 and 80 wt.% glycerol-monostearate (GMS) for 30 min. in a blender and subsequently heated in an oven at 60, 65 und 80°C for 1 hour.

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Results:

- 1 = white powder, inhomogeneous
- 2 = white porous agglomerate, inhomogeneous
- 3 = white, opaque to homogeneous melt
- 4 = white, almost clear homogeneous melt

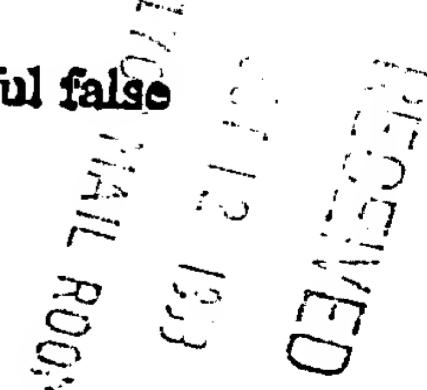
GMS wt. %	60°C	65°C	80°C
20	1	1	2
30	1	1	2
40	1	1	2
50	1	1	2
60	1	1	2
70	1	1	3
80	1	2	4

Conclusion:

None of the melts representative of the prior art was (absolutely) clear and homogeneous, optical clarity not being reached even at 80°C. Temperatures under 100°C thus are not suitable for the purpose of the invention requiring claimed components A) and B) to be miscible in the melt state recognizable by optical clarity of the melt (page 7, line 22, of the specification) so as to obtain a product as claimed.

As one skilled in this art, I consider the results obtained by the practice of the claimed invention to be unobvious and unexpected and of significant and material import.

3. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false



statements and the like so made are punishable by fine or imprisonment, or both, under
Section 1001 of Title 18 of the United States Code and that such willful false statements may
jeopardize the validity of this application or any patent issuing thereon.

4. Further, declarant saith not.

Manfred Assmus
Manfred Assmus

99-06-21
Date

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